## 510(k) SUMMARY
## AS REQUIRED BY SECTION 807.92(C)

**The Assigned 510(k) number is k071030**

JUN 2 9 2007

**Date of Summary:** June 26, 2007

**Common Name:** **hCG (Human Chorionic Gonadotropin)** Pregnancy Test

**Regulatory Information:**

1. Regulation section: 21 CFR part 862.1155, Human Chorionic Gonadotropin test system
2. Classification: Class II
3. Product Code: JHI, radioimmunoassay, human chorionic gonadotropin
4. Panel: Clinical Chemistry 75

**Name of Submitter**:
Applied DNA Technologies Inc.
6310 Nancy Ridge Dr. Suite 106
San Diego, CA 92121, USA

**Contact Person**:
Feng-Yu Lee

**Identification / Product Name**:
Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests

**Description**:
The Bionexia™ hCG Pregnancy Serum/Urine Test are distributed in both Cassette and Dipstick formats. Each test reagent strip contains mouse monoclonal anti-α-hCG antibody coated membrane and a dried chemical pad containing mouse monoclonal anti-β-hCG anybody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

**Intended Use**:
The Applied DNA Technologies Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests are rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in serum or urine specimen to help in the early determination of pregnancy.

The test kits are for health care professionals use including professionals at physician's office labs (POLs).

For a final Diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

**Predicate Kit**:
ACON One Step Pregnancy Urine/Serum Test is used as predicate device for ADT's Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests to compare their performance of required studies.

510(k) number for predicate devices is:
ACON One Step Pregnancy Urine/Serum Test K 041946

**Performance**:
The product performance characteristics of ADT's Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests were evaluated in the blind-labeled spiked control studies and blind-labeled clinical specimen correlation study including POLs site study. The results of these studies demonstrate ADT's Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests to be substantially equivalent to the performance characteristics of ACON's One Step Pregnancy Urine/Serum Test.

(I) Accuracy/Comparison study indicated 100% agreement in total of 95 clinical serum specimens and 94 clinical urine specimens evaluated, the study were conducted at two POL sites. (Additionally, 20 negative and 29 positive serum & urine specimens were reevaluated at a third site and similar results were obtained.)

**1. Serum sample**

| | | ***ACON One Step hCG Urine/Serum Test Card*** | | |
|---|---|---|---|---|
| | | + | - | Total |
| ***Bionexia™ Panel*** | + | 48 | 0 | 48 |
| | - | 0 | 47 | 47 |
| | Total | 48 | 47 | 95 |

**2. Urine sample**

| | | ***ACON One Step hCG Urine/Serum Test Card*** | | |
|---|---|---|---|---|
| | | + | - | Total |
| ***Bionexia™ Panel*** | + | 47 | 0 | 47 |
| | - | 0 | 47 | 47 |
| | Total | 47 | 47 | 94 |

(II) Sensitivity and Cross-reactivity

The Bionexia™ hCG Pregnancy Serum/Urine Test detects serum or urinary hCG at a concentration of 20mIU/ml or greater. The test has been standardized to the WHO Fourth International Standard 75/589.
Cross-reactivity study (Specificity) evaluated at negative (0 mIU/ml) and positive (20 mIU/ml) hCG specimens showed no cross-reaction:

| Substances (level) | % Non-cross-reactivity |
|---|---|
| hCG (20 mIU/ml) | 100% |
| hLH (300 mIU/ml) | 1,500% |
| hFSH (1000 mIU/ml) | 5,000% |
| hTSH (1,000 **μIU/mL**) | 5% |

(III) Reproducibility

Table 1: Serum controls

| Levels (mIU/ml) | 0 | | 10 | | 12.5 | | 15 | | 17.5 | | 20 | | 25 | | 30 | | 35 | | 40 | | 100 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Neg. / Pos. | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| Lot 1 | 25 | 0 | 25 | 0 | 20 | 5 | 11 | 14 | 2 | 23 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Lot 2 | 25 | 0 | 25 | 0 | 22 | 3 | 14 | 11 | 4 | 21 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Lot 3 | 25 | 0 | 25 | 0 | 21 | 4 | 12 | 13 | 2 | 23 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Lot 4 | 25 | 0 | 25 | 0 | 23 | 2 | 11 | 14 | 1 | 24 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Total No. | 100 | 0 | 100 | 0 | 86 | 14 | 48 | 52 | 9 | 91 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 |
| Percent. % | 100 | 0 | 100 | 0 | 86 | 14 | 48 | 52 | 9 | 91 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 |

Table 2: Urine controls

| Levels (mIU/ml) | 0 | | 10 | | 12.5 | | 15 | | 17.5 | | 20 | | 25 | | 30 | | 35 | | 40 | | 100 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Neg. / Pos. | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| Lot 1 | 25 | 0 | 25 | 0 | 23 | 2 | 11 | 14 | 1 | 24 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Lot 2 | 25 | 0 | 25 | 0 | 19 | 6 | 12 | 13 | 1 | 24 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Lot 3 | 25 | 0 | 25 | 0 | 21 | 4 | 14 | 11 | 3 | 22 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Lot 4 | 25 | 0 | 25 | 0 | 24 | 1 | 9 | 16 | 2 | 23 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |
| Total No. | 100 | 0 | 100 | 0 | 87 | 13 | 46 | 54 | 7 | 93 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 |
| Percent. % | 100 | 0 | 100 | 0 | 87 | 13 | 46 | 54 | 7 | 93 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 | 0 | 100 |

**Conclusion**:

Results of Accuracy, POL site study demonstrate the substantial equivalency between ADT's Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests and the ACON One Step Pregnancy Urine/Serum Test panel. It is also demonstrated that ADT's Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests are safe and effective in detecting human chorionic gonadotropin (hCG) in serum or urine sample to aid in the early determination of pregnancy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Applied DNA Technologies, Inc.
c/o Feng-Yu Lee
Vice President of Operation
26251 Verona Place
Mission Viejo, CA 92692

JUN 2 9 2007

Re: k071030
Trade/Device Name: Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) test system.
Regulatory Class: Class II
Product Code: JHI
Dated: March 25, 2007
Received: April 11, 2007

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): k071030

Device Name: **ADT's Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests**

Indications For Use:

The Applied DNA Technologies Bionexia™ hCG Pregnancy Serum/Urine Cassette and Dipstick Tests are rapid chromatographic immunoassays for the visual, qualitative detection of human chorionic gonadotropin (hCG) in serum or urine specimen at 20 mIU/mL and above to help in the early determination of pregnancy.

The test kits are for health care professionals use including professionals at physician's office labs (POLs).

For a final Diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071030